APR 2 5 2001

K010451

510(K) SUMMARY

February 13, 2001

a. Applicant's Name and Address

Novametrix Medical Systems, Inc.
56 Carpenter Lane
Wallingford, CT 06492

b. Contact Person

Robert H. Schiffman, R.A.C.
VP, Q.A./R.A.
(203) 284-2542
(203) 284-0753 (facsimile)

c. Name of Device

Device Names (Proprietary/Trade Names):	Marquette Compatible SpO_2 Sensors
Device Name (Common Name):	pulse oximetry sensor
Classification:	Accessory to an oximeter. Class II, 21 C.F.R. 870.2700

d. Equivalent Devices

Substantial equivalence to the following legally marketed predicate devices with the same or similar indications for use has been demonstrated by a comparison of product features as well as testing to accepted industry standards. In addition, inter-device comparison studies and non-invasive controlled hypoxia studies were conducted to establish the sensor accuracy with various Marquette monitors and to ensure that the sensors meet their currently published accuracy specifications. The predicate devices are as follows:

1. Model 2001 Pulse Oximeter, Novametrix Medical Systems, Inc., K993979
2. Oxisat - Finger Sensor, GEMS Marquette, K934091
3. Adult/Neonatal Wrap Sensor, GEMS Marquette, K943817

e. Device Description

The Marquette-compatible pulse oximetry sensors are *modifications* of the present Novametrix pulse oximetry sensors and nearly identical to the Marquette pulse oximetry sensors. The Marquette-Compatible pulse oximetry sensors are intended to be used for continuous monitoring of SpO_2 during anesthesia and intensive care and in the emergency department. The pulse oximeter to which these sensors are connected calculates oxygen saturation by measuring a ratio based upon the absorbance of red and infrared light by oxyhemoglobin and deoxyhemoglobin and pulse rate by measuring the time between successive pulses.

f. Intended Use

The Marquette-compatible reusable finger and wrap sensors are intended to provide continuous, non-invasive monitoring of functional arterial oxygen saturation and pulse rate with the Marquette oximetry monitors or modules in multi-parameter systems in

neonatal, pediatric and adult patients in hospital, hospital-type facilities and intra-hospital transport environments such as the operating room, emergency department and intensive care units. The Marquette Compatible sensors are intended to be used by trained operators when pulse oximetry monitoring is required in the judgement of a physician.

g. Technological Characteristics

Pulse oximeters measure functional oxygen saturation and pulse rate with sensors that contain red and infrared light sources. Since oxygen saturated blood absorbs different amounts of light at each wavelength (red and infrared) as compared with unsaturated blood, the amount of light absorbed at each wavelength by the blood in each pulse can be used to calculate oxygen saturation. The light energy from red and infrared LEDs is beamed through a sample cell- a pulsating vascular bed, the patient's finger or toe for example. The remaining light energy not absorbed by the sample cell reaches a photodiode, on the opposing side of the sensor. The signal received by the photodiode is split into its red and infrared components, sampled, software filtered, processed using proprietary algorithms and displayed as a numerical value for functional oxygen saturation and as a waveform, the plethysogram.

The Marquette and Marquette compatible SpO_2 sensors are intended to be used only in Marquette monitors and as such use the same SpO_2 and pulse rate software algorithms to process the information from the sensor. As such, the comparison of the sensors has focused on materials, construction and performance of both the finger and wrap sensors.

h. Certification Statement

In accordance with the requirements of 21 CFR 807.87(j), the following certification is provided:

Novametrix Medical Systems, Inc. believes that all data and information submitted in this premarket notification are truthful and accurate and no material fact has been omitted.

Robert H. Schiffman 2/14/01

Robert H. Schiffman, R:A.C.
VP, Q.A./R.A.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 5 2001

Mr. Robert H. Schiffman
Novametrix Medical Systems, Inc.
56 Carpenter Lane
Wallingford, CT 06492

Re: K010451
Marquette-Compatible Reusable Finger and Wrap Sensors
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: February 15, 2001
Received: February 15, 2001

Dear Mr. Schiffman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010451

Device Name: Marquette-compatible reusable finger and wrap sensors

Indications For Use:

The Marquette-compatible reusable finger and wrap sensors are intended to provide continuous, non-invasive monitoring of functional arterial oxygen saturation and pulse rate with the Marquette oximetry monitors or modules in multi-parameter systems in neonatal, pediatric and adult patients in hospital, hospital-type facilities and intra-hospital transport environments such as the operating room, emergency department and intensive care units. The Marquette Compatible sensors are intended to be used by trained operators when pulse oximetry monitoring is required in the judgement of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010451

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)